information being claimed as CBI. The second copy must contain only information not claimed as CBI. The Agency will place the second copy of the submission in a public file. Failure to furnish a second copy of the submission when information is claimed as CBI in the first copy will be considered a presumptive waiver of the claim of confidentiality. The Agency will notify the applicant by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The applicant has 30 days from the date of receipt of notification to submit the required second copy. Failure to submit the second copy will cause the Agency to place the first copy in a public file.

(d) Applicants must substantiate all claims of CBI at the time the applicant asserts the claim, i.e., when the exemption application or supplement is submitted, by responding to the questions in paragraph (e) of this section. Failure to provide substantiation of a claim at the time the applicant submits the application will result in a waiver of the CBI claim, and the information may be disclosed to the public without further notice to the applicant.

(e) Applicants who assert any CBI claims must substantiate all claims by providing detailed responses to the following:

(1) Is this information subject to a patent or patent application in the United States or elsewhere? If so, why is confidentiality necessary?

(2) For what period do you assert a claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

(3) Has the information that you are claiming as confidential been disclosed to persons outside of your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Briefly describe measures taken by your company to guard against undesired disclosure of the information you are claiming as confidential to others.

(5) Does the information claimed as confidential appear or is it referred to in advertising or promotional materials for the product or the resulting end product, safety data sheets or other similar materials for the product or the resulting end product, professional or trade publications, or any other media available to the public or to your competitors? If you answered yes, indicate where the information appears.

(6) If the Agency disclosed the information you are claiming as confidential to the public, how difficult would it be for the competitor to enter the market for your product? Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

(7) Has the Agency, another Federal agency, or a Federal court made any confidentiality determination regarding this information? If so, provide copies of such determinations.

(8) How would your company's competitive position be harmed if the Agency disclosed this information? Why should such harm be considered substantial? Describe the causal relationship between the disclosure and harm.

(9) In light of section 14(b) of TSCA, if you have claimed information from a health and safety study as confidential, do you assert that disclosure of this information would disclose a process used in the manufacturing or processing of a product or information unrelated to the effects of asbestos on human health and the environment? If your answer is yes, explain.

PART 766—DIBENZO-PARA-DIOXINS/DIBENZOFURANS

Subpart A—General Provisions

Sec.

AUTHORITY: 15 U.S.C. 2603 and 2607.

SOURCE: 52 FR 21437, June 5, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 766.1 Scope and purpose.

(a) This part identifies requirements for testing under section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, to ascertain whether certain specified chemical substances may be contaminated with halogenated dibenzodioxins (HDDs)/dibenzofurans (HDFs) as defined in §766.3, and requirements for reporting under section 8 of TSCA, 15 U.S.C. 2607.

(b) Section 766.35(b) requires manufacturers and processors of chemical substances identified in §766.25 to submit to EPA:

(1) Any existing test data showing analysis of the chemical substances for concentrations of HDDs/HDFs, applicable protocols, and the results of the analysis for HDDs/HDFs, (2) allegations of significant adverse reactions to HDDs/HDFs, compiled in accordance with part 717 of this chapter, and (3) health and safety studies on the HDDs/HDFs, in accordance with applicable provisions of part 716 of this chapter.

(c) Section 766.35(a) requires manufacturers and, under certain circumstances, processors of chemical substances identified in §766.25 to submit letters of intent to test and protocols for the analysis of the chemical substances for the presence of HDDs/HDFs. Section 766.20 requires these manufacturers and processors to test their chemical substances for the presence of HDDs/HDFs. Any submissions must be in accordance with the EPA Procedures Governing Testing Consent Agreements and Test Rules contained in part 790 of this chapter and any modifications to such procedures contained in this part.

(d) Section 766.32 specifies conditions under which persons required to test may request an exclusion or waiver from testing.

(e) Deadlines for submission to EPA of protocols, reports, studies, and test results are specified in part 790, subpart C and §766.35.

(f) Sections 766.10, 766.12, 766.14, 766.16, and 766.18 prescribe analytical methods required; §766.27 prescribes target levels of quantitation (LOQ) for each congener for which quantitation is required.

(g) If results of existing tests or tests performed under this part indicate the presence of HDDs/HDFs in the identified chemical substance above the LOQ specified in §766.27, §766.35(c) requires the following additional reporting on the specified chemicals: production, process, use, exposure and disposal data under section 8(a) of TSCA; health and safety studies under section 8(d) of TSCA; and reports of allegations of significant adverse reactions under section 8(c) of TSCA. In some cases, additional reporting may be required of manufacturers reporting no contamination of the identified chemical substances under §766.35(c)(2).

(h) Section 766.38 requires manufacturers of chemical substances produced from chemical substances identified as possible precursors to HDD/HDF formation, to report on chemical substances produced from such precursors.

§ 766.2 Applicability and duration of this part.

(a) *Chemical substances subject to testing.* (1) This part is applicable to each person who, at any time during the duration of this part, manufactures (and/or imports), or processes, a chemical substance identified under §766.25.

(2) The duration of this part for any testing requirement for any chemical substance is the period commencing with the effective date of this part to the end of the reimbursement period, as defined in §766.3, for each chemical substance. All reporting requirements for any chemical substance listed under §766.25 shall be in effect for the

same period as the testing requirement.

(b) *Precursor chemical substances.* (1) This part is applicable to each person who manufactures (and/or imports) a chemical substance from any precursor chemical substance identified in § 766.38.

(2) The requirement for precursor reporting under § 766.38 shall be in effect until three years after the effective date of this part.

(3) Small manufacturers are exempt from reporting process and reaction condition data on chemical substances made from precursor chemical substances listed under § 766.38.

§ 766.3 Definitions.

The definitions in section 3 of TSCA and the definitions of §§ 704.3, 716.3, 717.3, and 790.3 of this chapter also apply to this part.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

Congener means any one particular member of a class of chemical substances. A specific congener is denoted by unique chemical structure, for example 2,3,7,8-tetrachlorodibenzofuran.

Dibenzofuran means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of bridges between the benzene rings. The bridges are a carbon-carbon bridge and a carbon-oxygen-carbon bridge at both substitution positions.

Dibenzo-p-dioxin or *dioxin* means any of a family of compounds which has as a nucleus a triple-ring structure consisting of two benzene rings connected through a pair of oxygen atoms.

Guidelines means the Midwest Research Institute (MRI) publication *Guidelines for the Determination of Polyhalogenated Dioxins and Dibenzofurans in Commercial Products*, EPA contract No. 68–02–3938; MRI Project No. 8201–A(41), 1985.

HDD or *2,3,7,8-HDD* means any of the dibenzo-p-dioxins totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; and 1,2,3,4,7,8,9.

HDF or *2,3,7,8-HDF* means any of the dibenzofurans totally chlorinated or totally brominated at the following positions on the molecular structure: 2,3,7,8; 1,2,3,7,8; 2,3,4,7,8; 1,2,3,4,7,8; 1,2,3,6,7,8; 1,2,3,7,8,9; 2,3,4,6,7,8; 1,2,3,4,6,7,8; and 1,2,3,4,7,8,9.

Homolog means a group of isomers that have the same degree of halogenation. For example, the homologous class of tetrachlorodibenzo-p-dioxins consists of all dibenzo-p-dioxins containing four chlorine atoms. When the homologous classes discussed in this part are referred to, the following abbreviations for the prefix denoting the number of halogens are used:

tetra-, T (4 atoms)
penta-, Pe (5 atoms)
hexa-, Hx (6 atoms)
hepta-, Hp (7 atoms)

HRGC means high resolution gas chromatography.

HRMS means high resolution mass spectrometry.

Level of quantitation or *LOQ* means the lowest concentration at which HDDs/HDFs can be reproducibly measured in a specific chemical substance within specified confidence limits, as described in this part.

Polybrominated dibenzofurans refers to any member of a class of dibenzofurans with two to eight bromine substituents.

Polybrominated dibenzo-p-dioxin or *PBDD* means to any member of a class of dibenzo-p-dioxins with two to eight bromine substituents.

Polychlorinated dibenzofuran means any member of a class of dibenzofurans with two to eight chlorine substituents.

Polychlorinated dibenzo-p-dioxin or *PCDD* means any member of a class of dibenzo-p-dioxins with two to eight chlorine substituents.

Polyhalogenated dibenzofuran or *PHDF* means any member of a class of dibenzofurans containing two to eight chlorine, bromine, or a combination of chlorine and bromine substituents.

Polyhalogenated dibenzo-p-dioxin or *PHDD* means any member of a class of dibenzo-p-dioxins containing two to

eight chlorine substituents or two to eight bromine substituents.

Positive test result means: (1) Any resolvable gas chromatographic peak for any 2,3,7,8-HDD or HDF which exceeds the LOQ listed under § 766.27 for that congener, or (2) exceeds LOQs approved by EPA under § 766.28.

Precursor means a chemical substance which is not contaminated due to the process conditions under which it is manufactured, but because of its molecular structure, and under favorable process conditions, it may cause or aid the formation of HDDs/HDFs in other chemicals in which it is used as a feedstock or intermediate.

QA means quality assurance.

QC means quality control.

Reimbursement period means the period that begins when the data from the last test to be completed under this part for a specific chemical substance listed in § 766.25 is submitted to EPA, and ends after an amount of time equal to that which had been required to develop that data or 5 years, whichever is later.

TSCA means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq*.

[52 FR 21437, June 5, 1987, as amended at 78 FR 72828, Dec. 4, 2013]

§ 766.5 Compliance.

Any person who fails or refuses to comply with any aspect of this part is in violation of section 15 of TSCA. Section 15(1) makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) makes it unlawful for any person to fail or refuse to submit information required under this part. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17 of TSCA, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 766.7 Submission of information.

(a) All information (including letters of intent, protocols, data, forms, studies, and allegations) submitted to EPA under this part must bear the applicable Code of Federal Regulations (CFR) section number (e.g., § 766.20).

(b) You must use the CISS tool to complete and submit all data, reports, and other information required under this part except for records and reports of allegations of significant adverse reactions, which must be submitted in accordance with paragraph (c) of this section.

(1) Submissions must be submitted to EPA via CDX.

(2) To access the CISS tool go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html*.

(c) You must submit records and reports of allegations of significant adverse reactions and the accompanying cover letters by one of the following methods:

(1) Mail, preferably certified, to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions.

(2) Hand delivery to OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave. NW., Washington, DC, ATTN: Dioxin/Furan report part 766, Allegations of significant adverse reactions. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation.

[78 FR 72828, Dec. 4, 2013]

§ 766.10 Test standards.

Testing required under subpart B of this part must be performed using the protocols submitted to and reviewed by the EPA expert panel established under § 766.28. All new data, documentation, records, protocols, specimens, and reports generated as a result of testing under subpart B of this part must be fully developed and retained in accordance with part 792 of this chapter. These items must be made available during an inspection or submitted to

EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to EPA in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs) published in part 792 of this chapter. Sponsors must notify the laboratory that the testing is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the testing abide by the TSCA GLP standards. At the time test data are submitted, manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

§ 766.12 Testing guidelines.

Analytical test methods must be developed using methods equivalent to those described or reviewed in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products*. Copies are available from the Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S.Environmental Protection Agency, Room E–543B, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 544–0551. Publicly available docket materials are available at the addresses in § 700.17(b)(1) and (2) of this chapter.

[60 FR 34466, July 3, 1995, as amended at 77 FR 46292, Aug. 3, 2012]

§ 766.14 Contents of protocols.

Protocols should include all parts of the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, as stated in the Guidelines. For each chemical substance and each process, the manufacturer must submit a statement of how many grades of the chemical substance it produces, a justification for selection of the specific grade of chemical substance for testing, specific plans for collection of samples from the process stream, naming the point of collection, the method of collecting the sample, and an estimate of how well the samples will represent the material to be characterized; a description of how control samples (blanks) and HDD/HDF-reinforced control samples, or isotopically labeled compounds (standards) and duplicate samples will be handled; a description of the chemical extraction and clean up procedures to be used; how extraction efficiency and measurement efficiency will be established; and a description of instrument hardware and operating conditions, including type and source of columns, carrier gas and flow rate, operating temperature range, and ion source temperature.

§ 766.16 Developing the analytical test method.

Because of the matrix differences of the chemicals listed for testing, no one method for sample selection, preparation, extraction and clean up is prescribed. For analysis, High Resolution Gas Chromatography (HRGC) with High Resolution Mass Spectrometry (HRMS) is the method of choice, but other methods may be used if they can be demonstrated to reach the target LOQs as well as HRGC/HRMS.

(a) *Sample selection*. The chemical product to be tested should be sampled so that the specimens collected for analysis are representative of the whole. Additional guidance for sample selection is provided under § 766.12.

(b) *Sample preparation*. The sample must be mechanically homogenized and subsampled as necessary. Subsamples must be spiked or reinforced with surrogate compounds or with standard stock solutions, and the surrogates or standards must be thoroughly incorporated by mechanical agitation. Additional guidance is provided under § 766.12.

(c) *Sample extraction and cleanup*. The spiked samples must be treated to separate the HDDs/HDFs from the sample matrix. Methods are reviewed in the Guidelines under § 766.12, but the final method or methods are left to the discretion of the analyst, provided the instrumental response of the surrogates meets the criteria listed in the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, Appendixes B and C of the Guidelines. Cleanup techniques are described in the Guidelines. These

are chosen at the discretion of the analyst to meet the requirements of the chemical matrix.

(d) *Analysis.* The method of choice is High Resolution Gas Chromatographic/High Resolution Mass Spectrometric Determination, (HRGC/HRMS) but alternate methods may be used if the manufacturer can demonstrate that the method will reach the target LOQs as well as HRGC/HRMS. Specific operating requirements are found in the Guidelines.

§ 766.18 Method sensitivity.

The target level of quantitation required under § 766.27 for each HDD/HDF congener is the level which must be attempted for each resolved HRGC peak for that congener. For at least one product sample, at least two analyses of the same isotopically labeled HDD/HDF internal calibration standards spiked to a final product concentration equal to the LOQ for that congener must be reproducibly extracted, cleaned up, and quantified to within ±20 percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 50 to 150 percent of the amount spiked, and the results must be corrected for recovery.

Subpart B—Specific Chemical Testing/Reporting Requirements

§ 766.20 Who must test.

(a) Any person who manufactures, imports, or processes a chemical substance listed in § 766.25 must test that chemical substance and must submit appropriate information to EPA according to the schedules described in § 766.35. Chemical substances manufactured, imported or processed between January 1, 1984 and the date of promulgation of this part are subject to testing upon the effective date of this part. All other chemical substances are subject to testing immediately upon manufacture, import or processing. EPA expects that only manufacturers and importers will perform testing, and that the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the cost of testing. However, processors will be called upon to sponsor testing should manufacturers and importers fail to do so. A processor may apply for an exemption from testing upon certification to EPA that a manufacturer or importer is testing the chemical substance which that person processes.

(b) If no manufacturer or importer described in § 766.20 submits a letter of intent to perform testing within the period described under § 766.35(a), or an exemption application under § 790.45(a), or a request for an exclusion or waiver under § 766.32, EPA will issue a notice in the FEDERAL REGISTER to notify all processors of that chemical substance. The notice will state that EPA has not received any of the documents described in the previous sentence, and that current processors will have 30 days to submit either a letter of intent to perform the test or submit an exemption application.

(c) If no manufacturer, importer or processor submits a letter of intent to perform testing of a specific chemical substance produced by a specific process, EPA will notify all manufacturers, importers, and processors, either by notice in the FEDERAL REGISTER or by letter, that all exemption applications will be denied and that within 30 days all manufacturers, importers, and processors will be in violation of this part until a proposed study plan is submitted for required testing.

(d) Manufacturers, importers, and processors who are subject to this part must comply with the test rule development and exemption procedures in part 790 of this chapter, except as modified in this part.

§ 766.25 Chemical substances for testing.

(a) *Listing of chemical substances.* Chemical substances required to be tested for HDDs/HDFs under this rule are listed in this section. The listing is by Chemical Abstracts Service (CAS) Number and common name.

NOTE: For purposes of guidance only, EPA lists the chemical substances subject to testing under this part in two classes—those

known to be manufactured or imported between January 1, 1984, and promulgation of this part, and those not known to be manufactured or imported at the time of promulgation of this part.

(1) *Chemicals substances known to be manufactured between January 1, 1984 and date of promulgation of this part.*

CAS No.	Chemical name
79–94–7	Tetrabromobisphenol-A.
118–75–2	2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.
118–79–6	2,4,6-Tribromophenol.
120–83–2	2,4-Dichlorophenol.
1163–19–5	Decabromodiphenyloxide.
4162–45–2	Tetrabromobisphenol-A-bisethoxylate.
21850–44–2	Tetrabromobisphenol-A-bis-2,3-dibromopropyl ether.
25327–89–3	Allyl ether of tetrabromobisphenol-A.
32534–81–9	Pentabromodiphenyloxide.
32536–52–0	Octabromodiphenyloxide.
37853–59–1	1,2-Bis(tribromophenoxy)-ethane.
55205–38–4	Tetrabromobisphenol-A diacrylate.

(2) *Chemicals not known to be manufactured between January 1, 1984 and the date of promulgation of this part.*

CAS No.	Chemical name
79–95–8	Tetrachlorobisphenol-A.
87–10–5	3,4′,5-Tribromosalicylanilide.
87–65–0	2,6-Dichlorophenol.
95–77–2	3,4-Dichlorophenol.
95–95–4	2,4,5-Trichlorophenol.
99–28–5	2,6-Dibromo-4-nitrophenol.
120–36–5	2[2,4-(Dichlorophenoxy)]-propionic acid.
320–72–9	3,5-Dichlorosalicyclic acid.
488–47–1	Tetrabromocatechol.
576–24–9	2,3-Dichlorophenol.
583–78–8	2,5-Dichlorophenol.
608–71–9	Pentabromophenol.
615–58–7	2,4-Dibromophenol.
933–75–5	2,3,6-Trichlorophenol.
1940–42–7	4-Bromo-2,5-dichlorophenol.
2577–72–2	3,5-Dibromosalicylanilide.
3772–94–9	Pentachlorophenyl laurate.
37853–61–5	Bismethylether of tetrabromobisphenol-A.
	Alkylamine tetrachlorophenate.
	Tetrabromobisphenol-B.

(b) *Grade to be tested.* If the same process is used to manufacture all grades of the same chemical substance, only one grade need be tested. The grade to be tested must be the grade subject to the most intense heat and alkalinity for the longest duration of time, manufactured under each different process. If the heat, alkalinity and duration of reaction do not differ for various grades, the test substance must be the grade of chemical substance with the highest volume of sales.

§ 766.27 Congeners and LOQs for which quantitation is required.

Quantitation at the target LOQ shown for each of the following HDDs/HDFs which may be present in the chemical substances is required for the chemical substances listed under § 766.25. Analysis must take place for either chlorinated or brominated dibenzodioxins or dibenzofurans, whichever is predominantly expected to occur in the chemical substance to be tested. Only chlorinated and brominated congeners need be quantified; for chemical substances containing predominantly chlorine atoms, only congeners totally chlorinated at the numbered positions need be quantified; for chemical substances containing predominantly bromine atoms, only congeners totally brominated at the numbered positions need be quantified.

Chlorinated dioxins	Brominated dioxins	LOQ
2,3,7,8-TCDD	2,3,7,8-TBDD	0.1 ppb.
1,2,3,7,8-PeCDD	1,2,3,7,8-PeBDD	0.5 ppb.
1,2,3,4,7.8-HxCDD	1,2,3,4,7,8-HxBDD	2.5 ppb.
1,2,3,6,7,8-HxCDD	1,2,3,6,7,8-HxBDD	2.5 ppb.
1,2,3,7,8,9-HxCDD	1,2,3,7,8,9-HxBDD	2.5 ppb.
1,2,3,4,6,7,8-HpCDD	1,2,3,4,6,7,8-HpBDD	100 ppb.
2,3,7,8-TCDF	2,3,7,8-TBDF	1 ppb.
1,2,3,7,8-PeCDF	1,2,3,7,8-PeBDF	5 ppb.
2,3,4,7,8-PeCDF	2,3,4,7,8-PeBDF	5 ppb.
1,2,3,4,7,8-HxCDF	1,2,3,4,7,8-HxBDF	25 ppb.
1,2,3,6,7,8-HxCDF	1,2,3,6,7,8-HxBDF	25 ppb.
1,2,3,7,8,9-HxCDF	1,2,3,7,8,9-HxBDF	25 ppb.
2,3,4,6,7,8-HxCDF	2,3,4,6,7,8-HxBDF	25 ppb.
1,2,3,4,6,7,8-HpCDF	1,2,3,4,6,7,8-HpBDF	1 ppm.
1,2,3,4,7,8,9-HpCDF	1,2,3,4,7,8,9-HpBDF	1 ppm.

§ 766.28 Expert review of protocols.

EPA will gather a panel of experts in analysis of chemical matrices for HDDs/HDFs to review the protocols for testing submitted to EPA. The panel members will be employees of EPA and/or of other U.S. Government agencies who have had experience in analysis of chemical matrices and/or chemical wastes for HDDs/HDFs. The panel will recommend to the Director, EPA Office of Pollution Prevention and Toxics, whether the protocol submitted is likely to allow analysis down to the target LOQs, or if not, whether the protocol represents a good faith effort on the part of the tester to achieve the

lowest possible LOQs. The final determination to accept or reject the protocol will be made by the Director, Office of Pollution Prevention and Toxics. EPA will review the submitted protocols as rapidly as possible and will complete the review within 90 days after receipt. EPA may require submission of revised protocols. Comments and recommendations will be transmitted to the submitter, and if revisions are required, a final protocol must be submitted to EPA within 90 days after EPA transmits such recommendations.

§ 766.32 Exclusions and waivers.

(a) *Reasons for exclusions and waivers.* Any person subject to the testing requirements of this part may request an exclusion or waiver from testing for any one of the following reasons:

(1) *Exclusions may be granted if.* (i) Testing of the appropriate grade of the chemical substance has already been carried out, either analytical testing at the lowest LOQ possible, with appropriate QA/QC, or a well-designed bioassay with appropriate QA/QC or;

(ii) Process and reaction conditions of the chemical substance such that no HDDs/HDFs could be produced under those conditions;

(2) *Waivers may be granted if.* (i) A responsible company official certifies that the chemical substance is produced only in quantities of 100 kilograms or less per year, only for research and development purposes; or

(ii) In the judgement of EPA, the cost of testing would drive the chemical substance off the market, or prevent resumption of manufacture or import of the chemical substance, if it is not currently manufactured, and the chemical substance will be produced so that no unreasonable risk will occur due to its manufacture, import, processing, distribution, use, or disposal. (In this case, the manufacturer must submit to EPA all data supporting the determination.)

(iii) Waivers may be appropriately conditioned with respect to such factors as time and conditions of manufacture or use. The grade of decabromodiphenyl oxide produced by Dow Chemical Company (Dow) for the National Toxicology Program (NTP) bioassay on that chemical is excluded from the testing requirement under this part. Provided, however, that this exclusion will not apply if Dow fails to supply to EPA within 60 days of the effective date of this section evidence showing which grade was used for the NTP bioassay.

(b) *Timing.* Exclusion or waiver requests and detailed supporting data must be submitted to EPA within 60 days from the effective date of this part for persons manufacturing, importing or processing a chemical substance as of the date of promulgation, or 60 days prior to the date of resumption of manufacture or import for a chemical substance produced by a specific process if the chemical substance is not manufactured, imported or processed as of the date of promulgation.

(c) *Publication.* Within 10 days of receipt of any exclusion or waiver request, EPA will issue in the FEDERAL REGISTER a notice of such receipt. EPA will also issue a notice of its decision on each exclusion or waiver request within 60 days of receipt.

(d) *Decision.* The EPA Director of the Office of Pollution Prevention and Toxics will make the decision to grant or deny waivers or exclusions.

§ 766.35 Reporting requirements.

(a) *Letters of intent, exemption applications, and protocols*—(1) *Letters of intent.* (i) Persons who have manufactured or imported chemical substances listed under § 766.25 between January 1, 1984, and the effective date of this part are required to submit under § 790.45 of this chapter a letter of intent to test or an exemption application. These letters must be submitted no later than September 3, 1987.

(ii) Persons who commence manufacture, import or processing of a chemical substance listed under § 766.25 that has not been manufactured, imported or processed between January 1, 1984 and the effective date of this part must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import, or processing of the chemical substance, a letter of intent to test or an exemption application.

(iii) Persons who commence manufacture, import or processing of a

chemical substance listed under § 766.25 between the effective date of this part and the end of the reimbursement period for that particular chemical substance produced by a specific process must submit under § 790.45 of this chapter, within 60 days after the commencement of manufacture, import or processing of the chemical substance, a letter of intent to test or an exemption application.

(2) *Protocols.* (i) Each person who is manufacturing or processing a chemical substance listed in § 766.25 as of the effective date of this part who submits a notice of intent to test under § 766.35(a)(1) must submit a protocol for the test as follows:

(A) The protocols for each chlorinated chemical substance produced by each process to be tested must be submitted to EPA no later than 12 months after the effective date of this part.

(B) The protocol for each brominated chemical substance produced by each process to be tested must be submitted to EPA no later than 24 months after the effective date of this part except for the following chemicals.

(*1*) The deadline for submitting the protocols for tetrabromobisphenol-A (CAS No. 79–94–7); 2,4,6 tribromophenol (CAS. No. 118–79–6); decabromodiphenyloxide (CAS No. 1163–19–5); and 1,2-bis(tribromophenoxy)-ethane (CAS No. 37853–59–1) is January 31, 1991.

(*2*) The deadline for submitting protocols for octabromodiphenyloxide (CAS No. 32536–52–0) and allyl ether of tetrabromobisphenol-A (CAS No. 25327–89–3) is January 31, 1991.

(*3*) The deadline for submitting protocols for pentabromodiphenyloxide (CAS No. 32534–81–9) is February 6, 1995. The deadline for submitting tetrabromobisphenol-A-bisethoxylate (CAS No. 4126–45–2) is January 31, 1991.

(*4*) The deadline for submitting protocols for 3,4′,5-tribromosalicylanilide (CAS No. 87–10–5) is September 5, 1990.

(ii) For chemical substances produced by a specific process not manufactured or processed as of the effective date of this part, a person who begins manufacture and submits a notice of intent to test must submit protocols for the test as follows:

(A) Except as noted for the submitter and substance specified in the following table, protocols for testing must be submitted 12 months after manufacture or importation begins for chlorinated chemical substances.

CAS No.	Submitter	Chemical	Due date
118–75–2	Rhone-Poulenc	2,3,5,6-tetrachloro-2,5-cyclohexaniene-1,4-dione	March 4, 1994

(B) Protocols for testing must be submitted 24 months after manufacture begins for brominated chemical substances.

(iii) For persons who have been granted exemptions, waivers or exclusions from testing, protocols must be submitted 12 months after expiration of the exemption, waiver or exclusion for chlorinated chemical substances, and 24 months after expiration of the exemption, waiver or exclusion for brominated chemical substances.

(b) *Information that must be submitted to EPA.* (1) Persons who manufacture or import a chemical substance listed under § 766.25 must report no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later, the results of all existing test data which show that chemical substance has been tested for the presence of HDDs/HDFs.

(2) Any manufacturer or importer of a chemical substance listed in § 766.25 in possession of unpublished health and safety studies on HDDs/HDFs is required to submit copies of such studies to EPA no later than October 5, 1987 or 90 days after the person first manufactures or imports the chemical substance, whichever is later. The following provisions of part 716 of this chapter apply to submission of these studies: §§ 716.3, 716.10(a) (1) and (4); 716.20(a) (1), (2), (3), (4), (7), (8) and (10); 716.25; 716.30; 716.35(a) (1), (2), and (4) [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; and 716.60(a)(2).

(3) No later than October 5, 1987 or 90 days after the person first manufactures or imports the substance listed in § 766.25, any manufacturer or importer of a chemical substance listed in § 766.25 must submit records required to be held under part 717 of this chapter on any HDDs/HDFs.

(4) *Test results.* (i) Test results must be submitted to EPA not later than 270 days after EPA's transmission of comments or 180 days after a final protocol is submitted to EPA, whichever is shorter, except as noted for the submitters and substances specified in the following table:

CAS No.	Submitter	Chemical	Due Date	Effective Date
79–94–7	Great Lakes	Tetrabromobisphenol-A	May 26, 1992	May 28, 1993
79–94–7	Ethyl	Tetrabromobisphenol-A	August 10, 1992	May 28, 1993
79–94–7	Ameribrom	Tetrabromobisphenol-A	April 15, 1994	September 29, 1995
87–10–5	Pfister	3,4′,5-tribromosalicylanilide	45 days after protocol approval	May 28, 1993
118–75–2	Rhone-Poulenc Inc.	2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione	July 5, 1996	June 30, 1997
118–79–6	Great Lakes	2,4,6-Tribromophenol	May 26, 1992	May 28, 1993
1163–19–5	Ameribrom	Decabromodiphenyloxide	April 15, 1994	September 29, 1995
1163–19–5	Ethyl	Decabromodiphenyloxide	May 26, 1992	May 28, 1993
1163–19–5	Great Lakes	Decabromodiphenyloxide	May 26, 1992	May 28, 1993
4162–45–2	Great Lakes	Tetrabromobisphenol-A-bisethoxylate	June 2, 1993	September 8, 1994
25327–89–3	Great Lakes	Allyl Ether of Tetrabromobisphenol-A	August 10, 1992	May 28, 1993
32534–81–9	Great Lakes	Pentabromodiphenyloxide	March 22, 1993	September 8, 1994
32534–81–9	Akzo Chemicals Inc.	Pentabromodiphenyloxide	February 6, 1995	September 29, 1995
32534–81–9	Ameribrom	Pentabromodiphenyloxide	March 22, 1993	September 8, 1994
32536–52–0	Ameribrom	Octabromodiphenyloxide	January 8, 1993	September 29, 1995
32536–52–0	Ethyl	Octabromodiphenyloxide	May 15, 1994	May 28, 1993
32536–52–0	Great Lakes	Octabromodiphenyloxide	May 26, 1992	May 28, 1993
37853–59–1	Great Lakes	1,2-bis(tribromophenoxy)ethane	January 24, 1995	September 29, 1995

(ii) For purposes of reporting test results to EPA, and for further reporting triggered by a positive test result under § 766.35(c), a positive test result is defined at § 766.3.

(iii) Reporting of test results must follow procedures set out in part 790 of this chapter, except as modified in this part.

(c) *Information required to be submitted to EPA after submission of a positive test result.* (1) Any person who submits a positive test result for a specific chemical substance listed under § 766.25 must submit to EPA no later than 90 days after the date of submission of the positive test result the following:

(i) A completed form (EPA 7710–51) for that chemical substance. The form and instructions are available online at *http://www.epa.gov/oppt/chemtest/ereporting/index.html*. One form must be submitted for each chemical substance for which a positive test result has been submitted.

(ii) Health and safety studies for the chemical substance for which a positive test result has been reported. The following provisions of part 716 of this chapter apply to submission of these studies: §§ 716.3; 716.10 (a) (1), (2), (3) and (4); 716.20; 716.25; 716.30; 716.35(a) (1), (2), and (4), [if applicable]; 716.35 (b) and (c); 716.40 (a) and (b); 716.50; 716.55; 716.60(a)(2).

(iii) Copies of records on the chemical substances required to be held under part 717 of this chapter.

(2) If a positive test result on a chemical substance is received from one person but not from others, EPA may issue a notice in the FEDERAL REGISTER listing that chemical substance and requiring any person manufacturing, importing or processing that chemical substance who has not submitted a positive test result to submit the information required in Part II of EPA Form 7710–51. Such a notice will be published only if EPA needs additional

process data to make a determination of unreasonable risk.

(d)–(e) [Reserved]

(f) *Effective date.* (1) The effective date of this final rule is July 6, 1987, except for paragraphs (a)(2)(i)(B) introductory text, (a)(2)(i)(B)(*1*), (a)(2)(i)(B)(*2*), (a)(2)(i)(B)(*3*), (a)(2)(i)(B)(*4*), the table in paragraph (a)(2)(ii)(A), and the table in paragraph (b)(4)(i) of this section.

(2) The effective date for paragraph (a)(2)(i)(B) introductory text, (a)(2)(i)(B)(*1*), (a)(2)(i)(B)(*2*), and (a)(2)(i)(B)(*4*), is May 21, 1991. The effective date of paragraphs (a)(2)(i)(B)(*3*), and the table in paragraph (a)(2)(ii)(A) is September 29, 1995. The effective date of paragraph (b)(4)(i) introductory text is May 28, 1993, and the effective date of the entries in the table in paragraph (b)(4)(i) is shown in the effective dates column of the table.

(3) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[52 FR 21437, June 5, 1987, as amended at 56 FR 23229, May 21, 1991; 57 FR 24960, June 12, 1992; 58 FR 30991, May 28, 1993, 58 FR 34205, June 23, 1993; 59 FR 46356, Sept. 8, 1994; 60 FR 31922, June 19, 1995; 60 FR 50433, Sept. 29, 1995; 60 FR 56955, Nov. 13, 1995; 62 FR 35105, June 30, 1997; 78 FR 72829, Dec. 4, 2013]

§ 766.38 Reporting on precursor chemical substances.

(a) *Identification of precursor chemical substances.* Precursor chemical substances are produced under conditions that will not yield HDDs and HDFs, but their molecular structure is conducive to HDD/HDF formation under favorable reaction conditions when they are used to produce other chemicals or products. The following precursor chemical substances are identified by Chemical Abstract Service (CAS) number and name.

CAS No.	Chemical name
85–22–3 ...	Pentabromoethylbenzene.
87–61–6 ...	1,2,3-Trichlorobenzene.
87–84–3 ...	1,2,3,4,5-Pentabromo-6-chloro-cyclohexane.
89–61–2 ...	1,4-Dichloro-2-nitrobenzene.
89–64–5 ...	4-Chloro-2-nitrophenol.
89–69–0 ...	2,4,5-Trichloronitrobenzene.
92–04–6 ...	2-Chloro-4-phenylphenol.
94–74–6 ...	4-Chloro-o-toloxy acetic acid.
94–81–5 ...	4-(2-Methyl-4-chlorophenoxy) butyric acid.
95–50–1 ...	o-Dichlorobenzene.
95–56–7 ...	o-Bromophenol.
95–57–8 ...	o-Chlorophenol.
95–88–5 ...	4-Chlororesorcinol.
95–94–3 ...	1,2,4,5-Tetrachlorobenzene.
97–50–7 ...	5-Chloro-2,4-dimethoxyaniline.
99–30–9 ...	2,6-Dichloro-4-nitroaniline.
99–54–7 ...	1,2-Dichloro-4-nitrobenzene.
106–46–7	p-Dichlorobenzene.
108–70–3	1,3,5-Trichlorobenzene.
108–86–1	Bromobenzene.
108–90–7	Chlorobenzene.
117–18–0	1,2,4,5-Tetrachloro-3-nitrobenzene.
120–82–1	1,2,4-Trichlorobenzene.
348–51–6	o-Chorofluorobenzene.
350–30–1	3-Chloro-4-fluoronitrobenzene.
615–67–8	Chlorohydroquinone.
626–39–1	1,3,5-Tribromobenzene.
827–94–1	2,6-Dibromo-4-nitroaniline.

(b) *Persons required to report.* All persons who manufacture or import a chemical product produced using any of the chemical substances listed in paragraph (a) of this section as feedstocks or intermediates must report no later than September 29, 1987. Small manufacturers and those manufacturers and importers who produce the precursor chemical substances in quantities of 100 kilograms or less per year only for research and development purposes are not required to report under this section

(c) *Data to be reported.* Manufacturers and importers of chemical products made from precursor chemical substances identified in paragraph (a) of this section must report process and reaction condition data on Part II of EPA Form 7710–51 for each chemical product. A separate EPA Form 7710–51 must be submitted for each chemical product reported, and the precursor chemical substance used must be identified. All forms must be submitted to EPA no later than September 29, 1987.

[52 FR 21437, June 5, 1987, as amended at 60 FR 31922, June 19, 1995]

PARTS 767–769 [RESERVED]

PART 770—FORMALDEHYDE STANDARDS FOR COMPOSITE WOOD PRODUCTS

Subpart A—General Provisions

Sec.